



# New Medicare Anti-Markup Pathology Billing Regulations Effective January 1, 2009

The Centers for Medicare and Medicaid Services (CMS) finalized changes to its anti-markup rules related to diagnostic testing services. The revisions appeared in Medicare's 2009 Physician Fee Schedule Final Rule published in the November 19, 2008 Federal Register. These revisions will impact how Medicare pays for a broad range of diagnostic tests including but not limited to anatomic pathology services.

## Brief history

In the November 7, 2007 Federal Register, CMS amended and expanded payment restrictions for diagnostic tests by tightening up its anti-markup provisions under the reassignment rules. After receiving many comments and questions, CMS delayed full implementation of the new rule until January 1, 2009. However, CMS did not exempt from this one-year delay the regulations related to its longstanding anti-markup of the technical component (TC) of purchased tests, new payment restrictions to the professional component (PC) of purchased tests, and its new regulation regarding anatomic pathology services performed off-site in a "condo or pod lab" arrangement. By doing so, CMS was attempting to close the loopholes in the self-referral regulations that allow for the operation of off-site "condo or pod labs," which, according to CMS, permit physicians to purchase or contract for anatomic pathology testing services and then realize a profit from referrals to labs and/or when billing Medicare.

In the July 7, 2008 Federal Register, CMS proposed and requested comments on two alternative proposals to better define "office of the billing physician" to meet the anti-markup exemption. The first alternative stated that a physician who is employed by or contracts with a **single** physician or physician organization is considered to "share a practice" with that physician or physician organization. CMS believes that when a physician provides his or her efforts for a single physician organization (whether those efforts are full-time or part-time), s/he has a sufficient nexus with that practice to justify not applying the anti-markup provision. CMS had also proposed a second alternative, which would exempt the anti-markup payment limitation to the TC and the PC that are performed onsite of the billing physician or other supplier.

## Where are we today?

Effective January 1, 2009, the revised anti-markup regulations for billing diagnostic tests to Medicare is based on a modified flexible approach of the two proposed alternatives driven by **who** performs the tests and **where** the tests are performed — to determine if the anti-markup payment limitations apply. CMS believes that these two "either or" alternatives will offer a simpler approach to preventing potentially abusive arrangements while providing flexibility in preserving non-abusive diagnostic testing arrangements.

When billing Medicare for pathology lab services, compliance should first be analyzed under alternative 1 criteria, and if that standard cannot be met, under alternative 2 on a test-by-test basis to determine whether or not the anti-markup payment limitations apply:

*Alternative 1* – Under the first criteria, where the performing physician (that is, the physician who supervises the TC or performs the PC, or both) performs substantially all (at least 75 percent) of his or her professional services for the billing physician or other supplier, the services furnished by the physician on behalf of the billing physician or other supplier will not be subject to the anti-markup payment limitation.

*Alternative 2* – If the first criteria cannot be met, then a dermatology practice should apply the second alternative standard on a test-by-test basis. Under this second "site-of-service" criteria, only the TC performed and supervised and the PC performed in the office of the billing physician by an employee or independent contractor physician will avoid application of the anti-markup payment limitation.

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In applying these two new anti-markup billing alternatives, CMS is trying to assess whether the performing or supervising pathologist actually “shares a practice” with the billing physician. All other arrangements that do not meet either of these two requirements are subject to Medicare’s anti-markup regulations and Medicare’s reimbursement may not exceed the lowest of the following amounts: **1) The performing supplier’s net charge to the billing physician or other supplier; 2) The billing physician or other supplier’s actual charge; or 3) The fee schedule amount for the test that would be allowed if the performing supplier billed Medicare directly.**

Thomas Olsen, M.D., chair of the American Academy of Dermatology’s Task Force on Dermatopathology, indicated that the Academy has submitted comments to CMS regarding these new anti-markup regulations as they relate to dermatology to ensure that the new rules do not have unintended negative consequences for patient access to timely and reliable pathology tests.

### Assessing the 2009 Anti-Markup Regulations and its Impact on Dermatology

#### 1. **Alternative 1: substantially all professional services option**

If a dermatology practice contracts with a pathologist, the pathologist must perform “**substantially all**” (i.e., **at least 75 percent**) of his/her professional services for the **same** dermatology practice billing Medicare. None of those services would then be subject to the anti-markup payment limitation. Under this arrangement, the pathologist supervising the TC or performing the PC, or both would be considered to share a practice with the dermatology practice if the pathologist furnishes “substantially all” (at least 75 percent) of his or her professional services through that dermatology practice. The pathologist would then be able to furnish up to 25 percent of his or her professional services to other medical practices acting as a locum tenens physician, or in other circumstances without disqualifying himself or herself from sharing a practice with the dermatology practice for which s/he provides the bulk (that is, at least 75 percent) of his or her professional services.

According to CMS, “substantially all” requirement is satisfied if the billing dermatology practice has a reasonable belief, when submitting a claim, that: the performing pathologist has furnished substantially all of his or her professional services through the billing dermatology practice for the period of 12 months prior to and including the month in which the service was performed; or the performing pathologist will furnish substantially all of his or her professional services through the billing dermatology practice during the following 12 months (including the month the service is performed).

#### 2. **Alternative 2: site-of-service option**

If the first option cannot be met, then a dermatology practice should apply the Alternative 2 criteria on a test-by-test basis. Under this “site-of-service” option, **only technical components performed and supervised and professional components performed in the billing dermatologist’s office will avoid the anti-markup payment limitation rules.**

The anti-markup payment limitation will apply if the TC is supervised by a pathologist who **does not**—within the meaning of Alternative 1—share a practice with the billing dermatology office or the TC does not meet the site-of-service requirements of Alternative 2 (that is, the TC was not conducted in the office of the billing dermatology practice and was not supervised in the office of the billing dermatology practice by a physician who is an owner, employee, or contractor of the billing dermatologist).

### “Purchased Tests”

CMS determined that using the concept of a “purchased TC or PC” as a separate basis for imposing an anti-markup payment limitation is unnecessary, redundant, and potentially confusing in light of its decision to finalize Alternative 1 and to allow arrangements that do not meet the requirements of Alternative 1 to avoid application of the anti-markup provisions if they meet, on a test-by-test basis, the requirements of Alternative 2.

## Medicare Pathology Billing Examples in Dermatology

- 1. A dermatologist who reads their own slides and purchases the slides from an outside lab will experience no change from past Medicare billing rules and will be able to:**
  - a. Bill Medicare for PC at full charge.
  - b. Bill Medicare for TC but cannot markup lab charge— or the lab can bill TC directly to Medicare.
- 2. A dermatology practice retains a dermatopathologist to read slides purchased from an outside lab:**
  - a. If the dermatopathologist performs the bulk of the service (at least 75% of work) for this group (under Alternative 1), the dermatology group can bill Medicare full charge for PC (not subject to anti-markup). Purchased slides (TC) cannot be marked up if billed to Medicare by practice or the lab can bill TC directly to Medicare.
  - b. If the dermatopathologist reads slides at the office of billing/ordering physician (under Alternative 2), the dermatology group can bill Medicare full charge for PC (not subject to the anti-markup). Purchased slides (TC) cannot be marked up if billed to Medicare by practice or the lab can bill TC directly to Medicare .
- 3. A dermatology practice puts a lab on-site to do the TC. Retains a part-time dermatopathologist to read on-site:**
  - a. The dermatology practice can bill Medicare for both TC and PC and may bill globally (under Alternative 2).
- 4. A dermatology practice puts a lab on site to do the TC. Retains a part-time dermatopathologist to read slides but not on-site:**
  - a. The dermatology practice can bill Medicare for the TC at full charge (under Alternative 2).
  - b. The dermatology practice can bill Medicare for the PC but can't mark up more than the dermatopathologist's salary and benefits (no overhead costs).
- 5. A dermatology practice in same building with other physician offices (i.e., urology, family practice, or gastroenterology):**
  - a. Can share ownership of on-site lab (in the same building) and bill Medicare full fees for the TC (under Alternative 2).
  - b. If a dermatopathologist reads on-site for these various groups, then groups can also bill Medicare for the PC (under Alternative 2)
- 6. A dermatology practice with multiple satellite locations has one lab at main office location:**
  - a. The dermatology practice can only bill Medicare full fees for TC at the main office and is subject to the anti-markup payment limitations at satellite offices
  - b. The dermatology practice can bill Medicare full fees for PC if a dermatopathologist reads slides at the satellite offices

**Disclaimer:** *The American Academy of Dermatology advises dermatology practices to consult with their practice attorneys when developing and structuring business arrangements to ensure compliance with Medicare's new requirements for billing pathology test services as well other federal rules related to the anti-kickback and self-referral "Stark" laws.*

## Additional Medicare clarification covering diagnostic services

### Definition of the Office of the Billing Physician or Other Supplier

According to CMS, the “office of the building physician or supplier” includes space in which diagnostic testing services are performed—that is in the “same building,” in which the ordering physician or ordering supplier regularly furnishes patient care (and more specifically, for physician organizations, in the same building in which the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally). Many of the potentially abusive condo/pod lab arrangements that led to CMS’ extension of the anti-markup provisions to the PC of diagnostic testing services [in 2008] involved independent contractor pathologists who performed services in off-site pathology labs. CMS maintained that those arrangements did not have the type of nexus with the group practice (that is, the pod labs were not within the same building in which the ordering physician provided substantially the full range of patient care services).

### Mobile Van

CMS’ revised definition of the “office of the billing physician or other supplier” does not cover a mobile van that is used in the parking lot of a building in which the physician group sees patients. “Same building,” of the physician self-referral regulations, specifically excludes a mobile vehicle, van, or trailer. Therefore, unless provided in a mobile unit that qualifies as a “centralized building”, diagnostic services provided in the parking lot of a building in which a physician group sees patients already would be subject to the physician self-referral restrictions and would not be protected under the in-office ancillary services exception.

### Net Charge

For the moment, CMS has declined to make any changes to what they allow to be included in the calculation of “net charge.” Previously, CMS has expressed concerns that, allowing billing physicians and other suppliers to recoup costs such as overhead in situations in which the anti-markup provisions apply, would undermine a purpose of the anti-markup payment limitation because the incentive to over-utilize (to recover capital outlays and other costs) would still be present. Therefore, where the billing physician or other supplier pays the performing supplier a fixed fee for the TC or the PC, the “net charge” is the fixed fee (exclusive of any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier). Where a fixed fee is not paid, the billing physician or other supplier is limited to the salary and benefits it paid to the performing supplier for the TC or PC. As CMS indicated in the 2008 PFS final rule, it is the responsibility of the billing entity to ascertain the amount it paid for the TC or PC. The billing entity should maintain contemporaneous documentation of the methodology and information used to calculate the net charge, and may do so in any reasonable manner.

To review Medicare’s final 2009 anti-markup regulations appearing in the November 19, 2008 Federal Register, please see the attached PDF link at <http://www.aad.org/pm/billing/medicare/doc/2009%20CMS%20Final%20Rule%20re%20Medicare%20Pathology%20Billing%20Section.pdf>